OCT 1 2010

GE Healthcare
510(k) Premarket Notification Submission

K102104

Section 5: 510(k) Summary

VIVID P3

OCT 1 2010

K102104

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	16-July-2010
Submitter:	WIPRO GE HEALTHCARE PRIVATE LTD. No. 4, Kadugodi Industrial Area Bangalore, Karnataka – 560067. India.
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare 9900 Innovation Dr. Wauwatosa, WI 53226 Telephone: 414-721-4214 Fax: 414-918-8275
Secondary Contact Person:	Gurunathan M Regulatory Affairs Leader- Product Wipro GE Healthcare Private Ltd Telephone: 91-80-4088-2108 Fax: 91-80-2841-1645
Device:	VIVID P3 Diagnostic Ultrasound Imaging System
Classification Names: Product Code:	Ultrasonic Pulsed Doppler Imaging System Ultrasonic Pulsed Echo Imaging System and Diagnostic Ultrasonic Transducer Primary - IYN - 21CFR 892.1550; IYO – 21CFR 892.1560 & Secondary – ITX – 21CFR 892.1570
Predicate Device(s):	GE Logiq e/i & Vivid e - K072797, GE Logiq P5/A5 K060993, GE Logiq P6 K073297, GE Vivid S5/S6 K092079
Device Description:	The Vivid™ P3 is a high performance, mobile Color Doppler Ultrasound Imaging system. This system is designed for cardiovascular applications and including abdominal, neonatal/pediatrics & intra-operative. It is integrated with keyboard control panel, LCD type video display and 9 interchangeable electronic-array transducers.

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Cardiac (adult and pediatric), Peripheral Vascular, Fetal/Obstetrics, Abdominal (including GYN), Pediatric, Small Organ (including breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Intra operative (abdominal, thoracic and peripheral), Musculo-skeletal Conventional, Urology (including prostate), Transrectal and Transvaginal.

Technology: The VIVID P3 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The VIVID P3 and its applications comply with voluntary standards as detailed in Section 9, 11, 15 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Management
- Requirement Reviews
- Design reviews
- Unit level testing (Module Verification)
- Integration Testing (System level verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, VIVID P3, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the VIVID P3 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

WIPRO GE Healthcare Private, Ltd.
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W Innovation Dr., RP-2138
WAUWATOSA WI 53226

OCT 1 2010

Re: K102104
Trade/Device Name: VIVID P3 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 3, 2010
Received: September 8, 2010

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the VIVID P3 Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C
E8Cs
8L
8C
5Cs
3S

11L
T739
6S

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Mark D O'Hara for

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known):

Device Name: VIVID P3

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Cardiac (adult and pediatric), Peripheral Vascular, Fetal/Obstetrics, Abdominal (including GYN), Pediatric, Small Organ (including breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Intra operative (abdominal, thoracic and peripheral), Musculo-skeletal Conventional, Urology (including prostate), Transrectal and Transvaginal.

Prescription Use: **Yes** AND/OR Over-The-Counter Use: **No**
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

for David G Brown

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P		
Abdominal [1]	P	P	P	P	P	P	P	P	P		[5,6]
Pediatric	P	P	P	P	P	P	P	P	P		[5,6]
Small Organ [2]	P	P	P		P	P	P	P	P		[5,6]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac [3]	P	P	P	P	P	P	P	P	P		[5]
Peripheral Vascular	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Superficial											
Other [4]	P	P	P	P	P	P	P	P	P		[5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		[5,6]
Transvaginal	P	P	P		P	P	P	P	P		[5,6]
Transuretheral											
Intraoperative	P	P	P		P	P	P	P	P		[5,6]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

for David G. Brown

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 4C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P		[5,6]
Abdominal [1]	P	P	P		P	P	P	P	P		[5,6]
Pediatric	P	P	P		P	P	P	P	P		[5,6]
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other [4]	P	P	P		P	P	P	P	P		[5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; Previously cleared on GE LOGIQ P5/A5 K060993

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

for David G. Brown

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with E8Cs Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		[5,6]
Abdominal [1]	P	P	P		P		P	P	P		[5,6]
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other [4]	P	P	P		P		P	P	P		[5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		[5,6]
Transvaginal	P	P	P		P		P	P	P		[5,6]
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (Previously cleared on GE LOGIQ P5/A5 K060993);

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

for David G. Brown

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 8L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric	P	P	P		P	P	P	P	P		[5,6]
Small Organ [2]	P	P	P		P	P	P	P	P		[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Superficial											
Other [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative	P	P	P		P	P	P	P	P		[5,6]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Prescription User (Per 21 CFR 801.109)

for David G. Brown

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 8C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P		P	P	P	P	P		[5]
Pediatric	P	P	P		P	P	P	P	P		[5]
Small Organ [2]	P	P	P		P	P	P	P	P		[5]
Neonatal Cephalic	P	P	P		P	P	P	P	P		[5]
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

David G. Brown

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 5Cs Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P		[5,6]
Abdominal [1]	P	P	P		P	P	P	P	P		[5,6]
Pediatric	P	P	P		P	P	P	P	P		[5,6]
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other [4]	P	P	P		P	P	P	P	P		[5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (Previously Cleared on GE LOGIQ P5/A5 K060993);

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

for David G. Brown

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P	P	P	P	P	P	P		[5,6]
Pediatric	P	P	P	P	P	P	P	P	P		[5,6]
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		[5,6]
Cardiac [3]	P	P	P	P	P	P	P	P	P		[5, 6]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

PRESCRIPTION USER (PER 21 CFR 801.109)

for David G. Brown

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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 11L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric	P	P	P		P	P	P	P	P		[5,6]
Small Organ [2]	P	P	P		P	P	P	P	P		[5,6]
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		[5,6]
Musculo-skeletal Superficial											
Other [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative	P	P	P		P	P	P	P	P		[5,6]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (Previously Cleared on GE LOGIQ P5/A5 K060993);

Notes: [1] Abdominal includes renal, GYN/Pelvic
[2] Small organ includes breast, testes and thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology/Prostate
[5] 3D Imaging Mode
[6] Needle guidance imaging
[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

PRESCRIPTION USER (PER 21 CFR 801.109)

for David G. Brown

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with T739 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]											
Pediatric											
Small Organ [2]	P	P	P		P	P	P	P	P		[5]
Neonatal Cephalic											
Adult Cephalic											
Cardiac [3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		[5]
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		[5]
Musculo-skeletal Superficial											
Other [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative	P	P	P		P	P	P	P	P		[5]
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes and thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

PRESCRIPTION USER (PER 21 CFR 801.109)

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(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104

Diagnostic Ultrasound Indications for Use Form

GE VIVID P3 with 6S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P	P	P	P	P	P	P		[5]
Pediatric	P	P	P	P	P	P	P	P	P		[5]
Small Organ [2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		[5]
Adult Cephalic	P	P	P	P	P	P	P	P	P		[5]
Cardiac [3]	P	P	P	P	P	P	P	P	P		[5]
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other [4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA;

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] 3D Imaging Mode

[6] Needle guidance Imaging

[*] Combined modes are B/M, B/PWD, B/CF/PWD, B/PDI, B/CF/CWD, B/CWD, B/THI, and B/CMM

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

for David G Brown

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102104